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Complete Specification entitled (54) METHOD OF FABRICATING PLIABLE POLYFILAMENTOUS PLASTIC STRANDS

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Related Art (56) -

The following statement is a full description of this invention, including the best method of performing it known to us :

This invention relates to an improvement in the fabrication of pliable plastic polyfilamentous strands.

Plastic strands, for example, braided or twisted polyethylene terephthalate threads, have certain physical and chemical properties superior to naturally occurring materials for many applications. Polyfilamentous polyethylene terephthalate threads, for example, are suitable for use as surgical sutures because of the high tensile strength and inertness thereof. However, the thread is very stiff relative to, for example, silk of equal tensile strength and/or diameter and this lack of pliability causes the knotting characteristics of the thread to be quite poor for surgical use. To this end, various methods have been disclosed in the art for modifying the lubricity and pliability of plastic threads such that the knotting properties are similar to those of silk threads.

Moreover, to make the polyfilamentous strand suitable for use, including surgical use, it has been necessary to reduce the elasticity and memory (tendency to return to original length) of the plastic polyfilamentous strand. This is accomplished by hot-stretching of the strand at a temperature above its glass transition temperature, which will permit a change in configuration without the introduction of internal stresses. Conveniently, the strand may be heated to its softening point. Tension is applied to the heated thread such that the thread is stretched, for example, up to its breaking point. Elongation of over 10% and particularly from about 20% up

to but not including the breaking point are suitable to reduce the elasticity and memory of the thread sufficiently. The temperature necessary to reduce or eliminate elasticity and memory is called the heat-setting temperature which is known for various plastic materials. For polyester terephthalate, a temperature of 320°F. or above will suffice, although temperatures of about 390°F. to 450°F. are preferred.

While the heating step is necessary in order to render the material useful for several applications, it is believed that the step may render a polyfilamentous strand even more than naturally stiff due to adhesion or cohesion between adjacent elements of the polyfilamentous material. In my U.S. Patent No. 3,257,702, hereby incorporated by reference, a method is described for treating pliable polyfilamentous braided strands by subjecting the strands after they have been hot stretched to repeated flexion in order to cause relative movement between adjacent filaments of the strand. It is believed that flexing of the hot-stretched strand, according to the method of U.S. Patent 3,257,702, reduces or eliminates the cohesive or adhesive forces present in the hot-stretched strand to provide softer and more pliable thread.

A method has now been discovered which is an improvement in the method described in U.S. Patent No. 3,257,702. In accordance with the method of the present invention, a hot-stretched polyfilamentous plastic strand, after cooling, is passed under tension over a

plurality of sharp edges, each edge being positioned to effect at least ~~about~~ a 30° change in direction of the passing strand. By the term "polyfilamentous plastic strand" as used herein and the appended claims is meant a unitary structure of a plurality of plastic filaments and includes plastic monofilaments and polyfilaments which have been twisted, braided, entangled, spun and the like. Illustrative of such strands are braided and twisted threads, sutures; strings, spun and continuous synthetic filament yarns, etc.

Treatment of the hot-stretched strand in this manner induces a consistent flexing uniformly throughout the entire strand. There is consequently provided a strand of improved softness and pliability since no area of this strand escapes flexing. In addition, the improvement of the invention offers reproducibility advantages since it enables repeated preparation of strands of like softness and pliability. Furthermore, the improved method of the invention permits easy adjustment of the degree and the rapidity of flexion applied so as to enable optimization of conditions with respect to whatever type strand is being flexed.

The edge over which the strand is passed may be any suitable element having a relatively sharp edge. By "sharp edge", as used in the specification and claims, is meant an edge that provides a sharp flex to the strand over which it is passed in accordance with the method of the invention that breaks free or loosens adhering or

cohering filaments of the strand. Thus, the edge of the element, over which the strand is passed, should not be so sharp as to cause severing, cutting or abraiding of the strand; nor should the edge have a radius of curvature so large as not to provide the desired sharp flex. Included within the sharp edges contemplated by the method of the invention are sharp angular edges which can be considered as having essentially a zero radius of curvature and cylindrical elements having a very small radius of curvature of say up to 1/32 inch as is found in edges having a diameter of up to 1/16 inch. The sharp edged-elements over which the strand is passed may be constructed out of any suitable solid hard material resistant to wear such as steel, ceramic and the like. The number of edges in the series over and around which the strand passes will vary depending upon the nature of the particular polyfilamentous strand, the tension applied, and the rate at which the strand is drawn around the elements. Use of too many edges in the series, however, should be avoided since an excess of edges will often cause the strand to break. A series of three edges has been found to provide satisfactory results.

Any arrangement of the edges that provides the desired degree in change of direction can be employed. Although an arrangement which gives a 30° change of direction as the strand passes around each edge provides sufficient flexion, an arrangement which effects at least ~~about~~ a 90° change is preferred. The rate at which the

strands are passed around the edge is not critical and during passage the strand may be drawn either partially around or completely around each of the elements as long as it is passed over the flex-inducing edge. The strands should be under sufficient tension as they are passed over the edges in order to induce the desired flex. Any tension which keeps the strand taut without breaking the strand can be employed. Tensioning devices known to the art may be employed for this purpose, if desired. The drawing of the strand may be accomplished manually or, if desired, any suitable automatic or mechanical means may be employed. It may be necessary to repeat the passage of the thread around the plurality of edges to achieve the desired degree of softness and pliability.

After the strand has been flexed in accordance with the method of the present invention it may, if desired, be subjected to any of the conventional treatments known in the art. For example, provision ~~Provision~~ of a lubricant, such as silicone wax or polytetrafluoroethylene, on the surface and in the interstices of a braided or twisted polyester suture provides a thread of improved pliability and knotting characteristics.

The following examples are included to further illustrate the present invention. In the examples, reference is made to the attached figures wherein:

Figure 1 is a perspective view of an apparatus effecting the flexing in accordance with the invention

Figure 2 is an enlarged perspective view of one of the sharp edged-elements employed in the apparatus of Figure 1.

Example I

A five/zero polyethylene terephthalate thread is stretched at approximately 390°F. to an elongation of approximately 50%. The hot-stretched thread is drawn from a supply 1 and manually threaded through an introductory guide 3, entrance opening 5, over the wick 7 of applicator indicated generally as 9, through exit opening 11, and around guides 13, 15, and 17, respectively, in the manner illustrated in Figure 1. The thread is then attached to take-up spool 9. The guides, each containing a sharp ceramic edge shown for instance in Figure 2 as 19, are arranged in a manner which will effect at least a 90° change of direction of the passing thread at each edge. The applicator 9 is composed of a container 21 provided with wick 7 and a guide structure 23 provided with the aforementioned entrance opening 5 and exit opening 11. The wick 7 is immersed in a cooling medium such as water. When take-up spool 9 is rotated, the hot-stretched thread is pulled over wick 7 of the applicator 9 where it is cooled by the application of the liquid cooling medium and then over the sharp edges of guides 13, 15, and 17. Hot-stretched thread flexed in this manner exhibits remarkably soft and pliable characteristics.

Example II

Thread softened according to Example I is gathered into a skein and immersed in an aqueous solution of Teflon (Registered Trade Mark) DuPont blend 2510 containing about 58% by weight of Teflon (Registered Trade Mark) (polytetrafluoroethylene) particles having an average particle size of 0.5 micron, diluted with water to a 1/25 concentration is used. Triton X-100 (Rohm and Haas) and agitation are used to keep the well dispersed.

The skein of thread is kept immersed in the Teflon dispersion for 15 minutes to permit the particles of Teflon lubricant to permeate into the interstices of the thread. While the immersion time can vary widely it has been found that 15 minutes is adequate for skeins weighing up to 50 pounds as determined by measuring the amounts of Teflon (Registered Trade Mark) picked up after final processing. Excess Teflon (Registered Trade Mark) is then removed to provide a thread which is extremely pliable and has knotting characteristics substantially identical to that of silk sutures.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. In a method for fabricating pliable polyfilamentous strands by subjecting a hot-stretched polyfilamentous plastic strand to repeated flexion to cause relative movement between adjacent filaments of said polyfilamentous strand to thereby provide a soft and pliable product, the improvement which comprises passing the strand under tension over a plurality of sharp edges, each edge being positioned to effect at least ~~about~~ a 30° change in direction of the passing strand.

2. The improvement of Claim 1 wherein a series of three edges are employed.

3. The improvement of Claim 1 wherein each edge effects at least ~~about~~ a 90° change in direction of the passing strand.

4. The improvement of Claim 1 wherein the polyester is polyethylene terephthalate.

5. The improvement of Claim 3 wherein each edge is the sharp ceramic edge of a guide pin.

6. An improved method of fabricating soft and pliable polyester surgical sutures which comprises stretching a braided or twisted polyfilamentous polyester strand up to 50% less than breaking point while maintaining the strand at least at the heat-setting temperature thereof and cooling said stretched strand, passing the strand under tension around a plurality of guide pins, each pin having a sharp edge over which the strand passes and being positioned to effect at least a 30° change in direction of the passing strand.

7. The method of Claim 6 wherein a lubricant is ~~provided on~~ applied to the surface and within the interstices of the softened suture after passing the strand over said edges.

8. The method of Claim 6 wherein a series of three guide pins are employed.

9. The method of Claim ~~6~~ 7 wherein the polyester is polyethylene terephthalate and the lubricant is polytetrafluoroethylene.

10. A method for fabricating pliable polyfilamentous strands substantially as herein described with reference to Example 1 or Example 11.

11. Pliable polyfilamentous strands substantially as hereinbefore described with reference to Example 1 or Example 11.

DATED THIS 7th day of AUGUST, 1969.

SUTURES, INC.

By its Patent Attorneys:

CLEMENT HACK & CO.

Fellows Institute of Patent Attorneys of Australia.

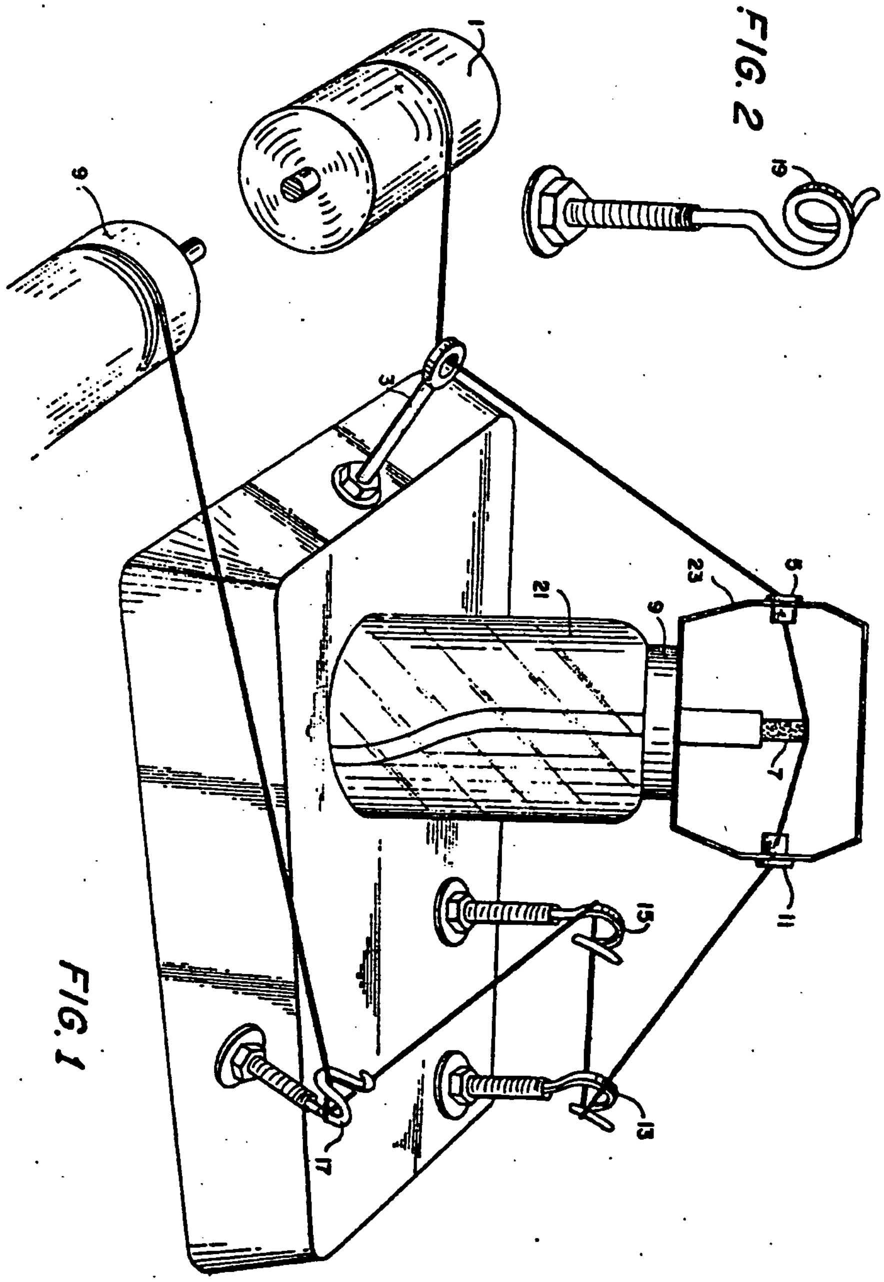

FIG. 1

FIG. 2

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